

Editorial: *Journal of Pediatric Psychology*—Statement of Purpose Section on Randomized Trials

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The future of our profession depends considerably on the extent to which we are able to design and conduct carefully conceived clinical trials of interventions targeting important clinical problems in pediatric psychology and on the effectiveness of our communication and dissemination of those results. Within the past few years, the *Journal of Pediatric Psychology* has made several appeals to its readership and put forth a variety of efforts to encourage the publication of randomized controlled trials of psychological interventions conducted in the context of pediatric health care and to enhance the broader impact of those publications. A 2003 issue of the journal included two papers (McGarth, Stinson, & Davidson, 2003; Stinson, McGrath, & Yamada, 2003) and an editorial (Brown, 2003) on the merits of applying the Consolidated Standards for Reporting Clinical Trials (CONSORT) criteria (Begg et al., 1996; Rennie, 2001) to treatment outcome studies reported in the journal. A subsequent 2005 special issue of the journal was dedicated to family-based interventions in pediatric psychology and this included reports of treatment outcome studies targeting varied clinical problems (Browne & Talmi, 2005; Ellis, Naar-King, Frey, Templin, Rowland, & Cakan, 2005; Kazak et al., 2005; Lobato & Kao, 2005). Most recently, Drotar (2005a,b) communicated the journal's intent to encourage the publication of papers reporting the results of intervention trials, papers illustrating or elucidating methodological, logistical, analytic, or ethical issues that pertain to treatment outcome studies and discussion of theoretical issues that may stimulate the development of clinical trials in pediatric psychology. A special section of the journal for treatment outcome papers was created. These efforts to stimulate articles reporting the results of randomized controlled trials have borne fruit. The journal has recently published quite a few examples of papers

that report carefully conducted randomized controlled trials of psychological interventions applied to problems appearing in pediatric health-care contexts.

Dr Drotar has renewed this commitment and assigned me, as a new Associate Editor, the responsibility for coordinating the reviews of manuscripts that report the results of randomized controlled trials. Through this statement of purpose, I hope to make myself busier in that role, but also to make my editorial quality of life somewhat more enjoyable and gratifying. In that spirit, I will offer the following suggestions to those planning future intervention trials and to those considering the submission of manuscripts reporting randomized trial results to the *Journal of Pediatric Psychology*.

Emulate Good Examples of Randomized Trial Reports

The value of a well-designed and conducted randomized trial is diminished if the results are not presented, analyzed, and interpreted in a clear and compelling manner. The *Journal of Pediatric Psychology* has published a number of very strong randomized trial papers in the past few years (Barakat et al., 2003; Ellis et al., 2005, 2007; Ievers-Landis et al., 2005; Kazak et al., 2005; Koontz, Short, Kalinyak, & Noll, 2004; Moore, Friman, Fruzzetti, & MacAleese, 2007; Robins, Smith, Glutting, & Bishop, 2005; Salmon, McGuigan, & Pereira, 2006; Stark, Janicke, McGrath, Macknee, Hommel, & Lovell, 2005; Warner et al., 2006; Wysocki et al., 2006). Prospective authors would be prudent to be familiar with papers like these that have successfully negotiated the peer review process and to emulate their positive elements. There are many other good examples to be found in other journals that publish pediatric psychology papers.

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Demonstrate Careful Attention to Ethical Issues

Many randomized trials assign participants to comparison groups that receive either no intervention or a diluted intervention such as an educational program. For example, randomized trials of psychological interventions often assign some participants to no-treatment control groups. Authors should clearly describe how such participants were protected from unacceptable deterioration relative to the measured treatment outcomes during the study. Similarly, psychological intervention studies often involve collection of norm-referenced measures of psychological adjustment and psychopathology. Authors should make clear how previously unrecognized evidence of clinically significant psychological problems was managed during the trial. In studies of group interventions, authors should be able to describe how the privacy and confidentiality of group participants were safeguarded. Finally, authors should provide a summary of any adverse effects or breaches of confidentiality experienced by participants related to either the assessment or intervention protocols employed during the study.

Verify Treatment Integrity

Confirmation that the intervention was delivered as planned and that there was no contamination of comparison groups is perhaps even more critical for behavioral, as opposed to pharmacological, intervention research. Authors should describe therapist qualifications and training, ongoing monitoring of treatment integrity, methods of ensuring consistency in intervention delivery across sites or therapists, and methods of detection and correction of violations of the intervention protocol. Related to this, the development of detailed intervention manuals facilitates replication of treatment effects at new sites or their application to different clinical problems. As part of its Strategic Plan, the Society of Pediatric Psychology is currently laying the groundwork for the creation of a repository for manuals describing empirically validated interventions.

Provide Information Pertinent to the Consolidated Standards for Randomized Trials (CONSORT) Criteria

The CONSORT criteria (Begg et al., 1996; Rennie, 2001) were put forth to ensure that journal articles reporting the results of randomized trials do so in a standardized

manner that provides crucial information to the reader that enables careful appreciation of key methodological details. While most randomized trials reflect some deviations from optimal conformity to these standards, authors should be familiar with the criteria and provide all of the information needed to allow the reader to evaluate the extent to which the criteria were met. The journal has provided a checklist for authors to use for this purpose.

Appreciate the Importance of Cost Effectiveness and Dissemination of the Intervention

The burgeoning science of cost-effectiveness evaluation has seen limited application in either pediatric psychology or clinical child psychology (Gold, Siegel, Russell & Weinstein, 1996). Nor have pediatric psychologists dedicated substantial attention to either evaluating or promoting the widespread dissemination of tested interventions into clinical practice (Glasgow & Emmons, 2007). Papers illustrating these approaches in reports of randomized trial results would be valuable contributions.

Consider Registration of your Clinical Trial

In recent years it has become evident that results of clinical trials of investigational drugs and medical devices, particularly negative results, are often never published. The need for mechanisms to increase public accountability among study sponsors and investigators has stimulated the call for a priori registration of clinical trials on websites such as www.clinicaltrials.gov and other registries. Most medical journals now require documentation of this type of registration for all papers reporting randomized trial results and many psychological journals are strongly encouraging this as well (Brown, 2006). The registration process on clinicaltrials.gov requires about 20–30 min for completion and this can be done even after a trial has been initiated.

Summary

The process of writing a noteworthy paper reporting randomized trial results begins with designing a good study that enables the author to clearly describe all aspects of the investigation, the results and their interpretation. Congratulations to those of you who have already made such contributions! For those who are planning or designing a future trial, analyzing data

from a completed one, or writing a report of the results of a completed randomized intervention trial for possible publication in this journal, I hope that this statement of purpose will help you to complete those tasks more skillfully. For those who have no intention of designing or conducting a randomized trial or disseminating the results of one, I hope that this discussion will help you to become a more discriminating reader of those papers.

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